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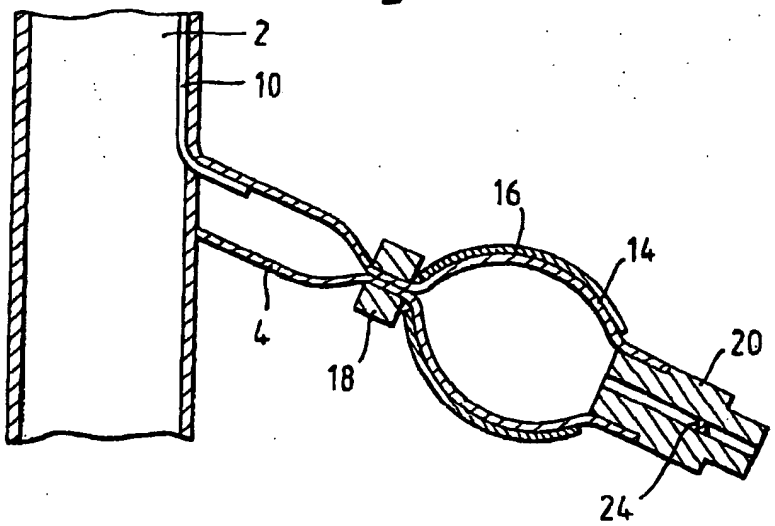
(54) Balloon catheter inflation

(57) A catheter for clinical use comprises a length of inflatable tubing which, towards the end to be inserted, is provided with an inflatable outer sleeve or balloon. Air or liquid may be fed to the balloon for inflation through a catheter tube or bore which runs along at least part of the length of the catheter tube wall. The catheter has an inflatable portion of tubing 14 which is normally pre-inflated and which is connected to the inflatable balloon, sealing means 18, 20 being provided for both ends of the inflatable portion, the inflatable portion being covered with a sleeve 16 of elastic material. In use and after insertion of the catheter a sealing means 18 is removed and the modulus of elasticity of the elastic sleeve causes the inflated sleeve to return to its original shape causing air or liquid previously in the inflatable portion to inflate the balloon at the inserted end of the catheter.

Fig. 3.



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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.
The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1982.

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Fig.1

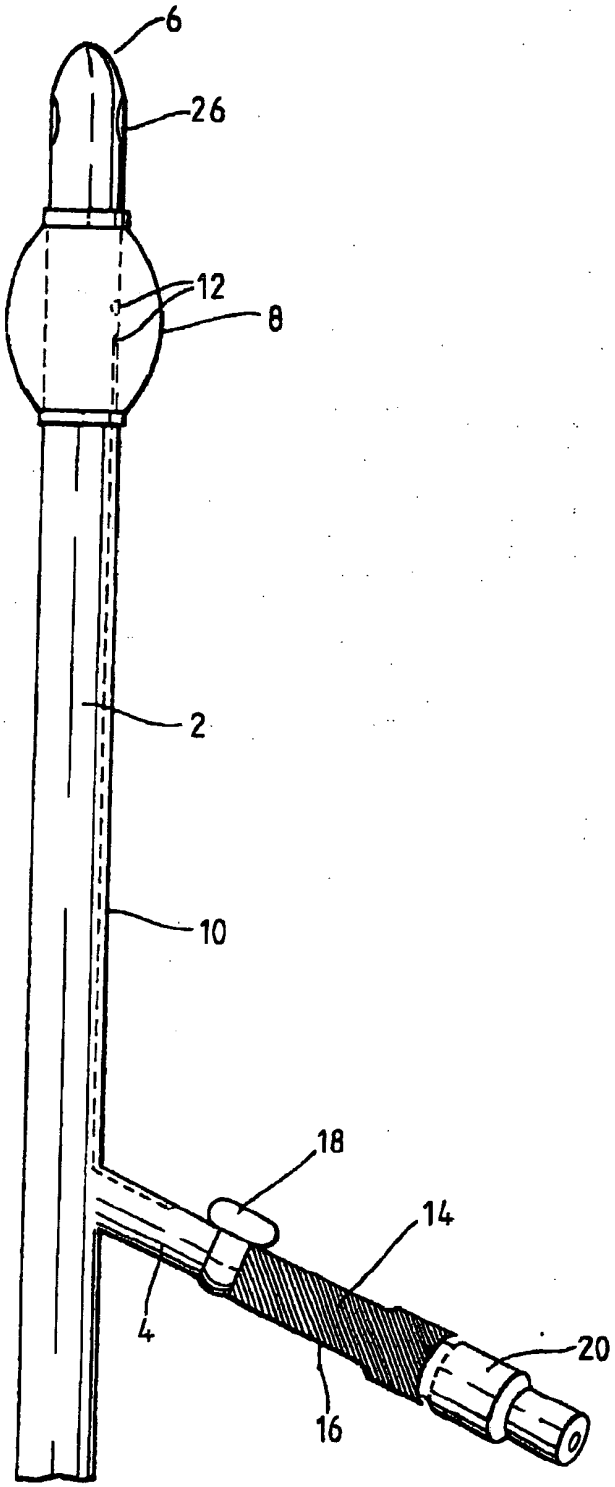

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Fig.2.

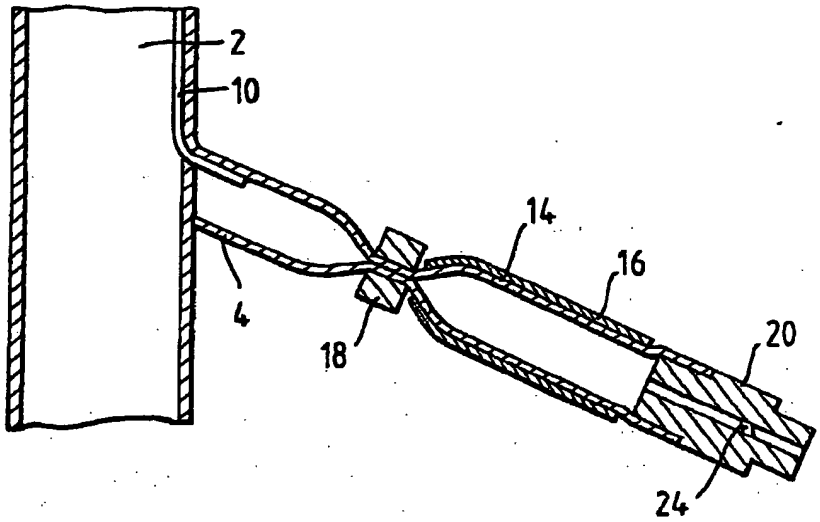
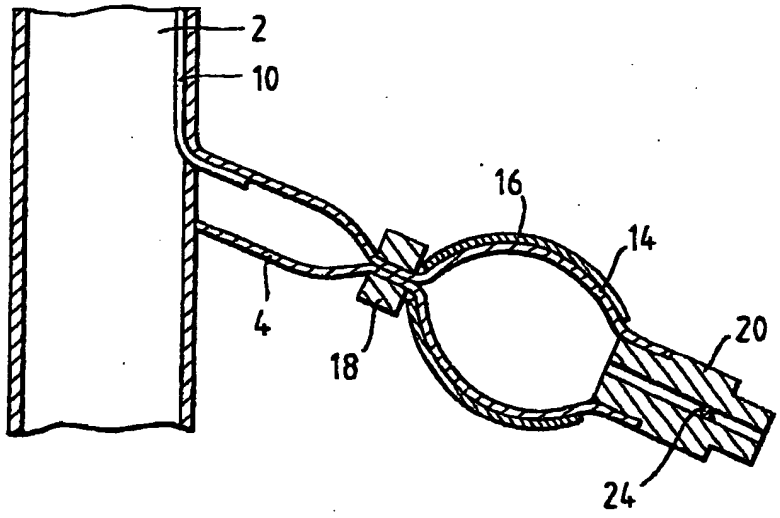


Fig.3.



CATHETER

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The invention relates to a catheter for clinical use, for insertion into the bladder or other body orifices or blood vessels.

A standard catheter comprises a length of flexible tubing which, towards the end to be inserted, is provided with an inflatable outer sleeve or balloon. The catheter is inserted into, for example the bladder, while the balloon is deflated. Once inserted the balloon is inflated with air or liquid, thus anchoring the catheter in the correct position without damaging any internal tissues.

Air or liquid may be fed to the balloon through a capillary tube or bore which runs along, at least part of, the length of the catheter tube wall and which has one open end within the inflatable balloon and the other open end at the air or liquid supply point. Such a catheter will hereafter be referred to as a catheter of the type described.

In one particular type of known catheter for use in the bladder, the air or liquid supply point comprises an inflatable portion on catheter tubing which is pre-inflated during manufacture with air or liquid and sealed at both ends to form an external balloon. With this external balloon in the inflated state the catheter is inserted into the appropriate position in the bladder.

The seal at the end of the balloon nearest the inserted end of the catheter is usually in the form of a fluid retaining clip which can be easily removed. After insertion, removal of the clip results in spontaneous transfer of the fluid in the external balloon through the capillary tube to inflate the internal balloon. A disadvantage of this type of pre-inflated catheter is that the most suitable manufacturing materials for internal use have a poor elastic memory. Thus although it is intended that the transfer of fluid from the external to the internal balloon will be spontaneous, in practice, this is not always the case because the external balloon has become deformed and does not automatically return to its original shape. A certain amount of manual pumping is required to force the fluid to the internal balloon. Further, having pumped the external balloon there is still a tendancy for the 'back-flow' of fluid because it takes a considerable time for the external balloon to fully contract to its original un-inflated state.

A catheter in accordance with the invention, is of the type described having an inflatable portion of tubing, forming part of or attached to the catheter tubing, sealing means being provided for both ends of the inflatable portion, the inflatable portion being covered with a sleeve of highly elastic material.

The inflatable portion of catheter tubing may be within a branch of the main catheter tube and of smaller diameter.

Preferably, one or both ends of the inflatable portion is reversibly sealed by a fluid retaining clip which closes the lumen of the catheter tube. The end of the inflatable portion through which it is inflated during manufacture may be reversibly sealed by a self-sealing rubber plug or a stopper incorporating a non-return valve.

The elastic sleeve is preferably a material which is resilient enough to return to its original shape when the inflatable portion is deflated, for example rubber. The elastic sleeve may be coated with a layer of an impermeable material or alternatively this layer may be applied to the inflatable portion of the catheter tubing before fitting of the sleeve. The thickness of the elastic sleeve is, for example 1mm. The wall of the inflatable portion of tubing may be at least 2mm thick.

In manufacture, the section of catheter tubing which will become the pre-inflated external balloon, is first fitted with a self-sealing plug or non-return valve. The elastic sleeve is then applied and a fluid retaining clip fitted to occlude the tubing at the opposite end to the non-return valve or plug. Fluid is injected into the portion via the valve or plug so that it inflates to form

the external balloon. The catheters are then sterilised and packaged for use.

In use the catheter is inserted into the bladder or other body vessel and the fluid retaining clip removed. The modulus of elasticity of the sleeve is such that it immediately returns to its original shape and air or liquid if forced out of the external balloon, through the capillary tube and into the internal balloon. Such a catheter is thus spontaneously self-inflating so that manual pumping is unnecessary and the back-flow of fluid is avoided. To remove the catheter from the bladder a syringe may be used to pierce the self-sealing plug or non-return valve and allow the fluid from the internal balloon to be withdrawn.

An advantage of a catheter in accordance with the invention is that whereas the degree of 'elastic memory' achievable with standard catheter tubing is limited because it must be of a non-toxic formulation, the sleeve may be made of any highly elastic material since it is always external to the body. A further advantage is that conventional catheters of the type described herein may be easily converted to catheters in accordance with the invention by fitting of the elastic sleeve at the last stage of the production cycle.

It is to be understood that apart from urological catheters the invention is applicable to endo-tracheal catheters or balloon dilatation catheters for use, for example, in embolectomy.

The invention will now be described by way of example with reference to the accompanying drawings in which :-

Figure 1 is a perspective view of a catheter in accordance with the invention.

Figure 2 is a cross-section of the self-inflating mechanism when the inflatable portion of the tube is deflated, and

Figure 3 is a cross-section of the self-inflating mechanism with the portion of the feed tube inflated to form the external balloon.

Referring to Figure 1 the catheter comprises a main catheter tube 2 and a catheter feed tube 4, the feed tube having a smaller diameter than the main tube. Towards the domed end 6 of the tube to be inserted into the bladder, there is provided an outer inflatable sleeve or balloon 8. Beyond the sleeve 8 are catheter outlet holes 26. Air or liquid is fed to the balloon 8 through a capilliary tube 10 and holes 12 in the wall of the main catheter tube 2.

The catheter feed tube 4 is provided with an inflatable portion 14 which is covered with an elastic sleeve 16. At the end of the inflatable portion 14, adjacent the inlet of the feed tube 4 to the main catheter tube 2, a removable fluid retaining clip 18 is provided to close the lumen of the feed tube 4. The distal end of the inflatable portion is provided with a stopper 20 incorporating a non-return valve 24 (see figure 2).

Referring now to Figures 2 and 3, during manufacture air or liquid is introduced into the inflatable portion 14 through the non-return valve 24 in the stopper 20. The valve 24 prevents the air or liquid from subsequently escaping. The inflatable portion is then as shown in Figure 3 in the form of a balloon where the outward pressure of the fluid on the walls of the tubing 14 is balanced by the inward force of the elastic sleeve 16.

The catheter is inserted into the baldder and the clip 18 removed. Contraction of the elastic sleeve 16 forces air or liquid from the external balloon through the capilliary tube 10 and into the balloon 4.When it is required to remove the catheter from the bladder, the non-return valve 24 is pierced with a syringe and the fluid from the internal balloon 4 may be withdrawn.

Thus the invention provides a catheter which, on the simple removal of a clip, becomes self-inflating. Apart from the manufacturing advantages mentioned herein, the inflation mechanism requires no manual pumping so that the time taken for catheter insertion and positioning is reduced and the procedure is generally simplified.

CLAIMS:-

1. A catheter of the type described having an inflatable portion of tubing forming part of, or attached to, the catheter tubing, sealing means being provided for both ends of the inflatable portion, the inflatable portion being covered with a sleeve of elastic material.

2. A catheter as claimed in Claim 1 wherein the inflatable portion forms part of a branch extending from and connecting to the main catheter tube but being of smaller diameter.

3. A catheter as claimed in either Claim 1 or 2 in which one or both ends of the inflatable portion is reversibly sealed by a fluid retaining clip which closes the lumen of the catheter tube.

4. A catheter as claimed in Claim 3 in which the end of the inflatable portion through which said portion may be inflated during manufacture is reversibly sealed by a safety sealing rubber plug or a stopper incorporating a non-return valve.

5. A catheter as claimed in any of the preceding claims in which the elastic sleeve is made of a material which is sufficiently resilient to return to its approximate original shape when the inflatable portion is deflated.

6. A catheter as claimed in Claim 5 wherein the elastic sleeve is made of rubber.

7. A catheter as claimed in either Claim 5 or 6 in which either the elastic sleeve or the inflatable portion of the catheter tube is coated with a layer of impermeable material.

8. A catheter substantially as hereinbefore described with reference to the accompanying drawings.

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